

Translation

PATENT COOPERATION TREATY

PCT/EP2003/014649



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0000054195	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/014649	International filing date (<i>day/month/year</i>) 19 December 2003 (19.12.2003)	Priority date (<i>day/month/year</i>) 20 December 2002 (20.12.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/82		
Applicant METANOMICS GMBH & CO. KGAA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of <u>5</u> sheets.
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 16 July 2004 (16.07.2004)	Date of completion of this report 08 March 2005 (08.03.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages _____ 1-72 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages _____, as originally filed
pages _____ 1-25 _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the drawings:
pages _____ 1/2-2/2 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the sequence listing part of the description:
pages _____ 1-29 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-24, 25(in part)

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1-24, 25 (in part)

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments)*:

Continuation of: I.6

1. The subject matter of the newly filed claims 1-25 does not go beyond the subject matter of the international application in the originally filed version. PCT Article 34(2)(b) is therefore formally satisfied.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

See the Supplemental Box.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-19	YES
	Claims	20-24	NO
Inventive step (IS)	Claims		YES
	Claims	1-24	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims		NO

2. Citations and explanations**See the Supplemental Box.**

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III and V

1. Reference is made to the following documents:

- D1: EP-A-0 930 367 (BASF AG; KERNFORSCHUNGSANLAGE JUELICH (DE)) 21 July 1999 (1999-07-21)
- D2: MONSCHAU N ET AL: "THREONINE ALDOLASE OVEREXPRESSION PLUS THREONINE SUPPLEMENTATION ENHANCED RIBOFLAVIN PRODUCTION IN ASHBYA GOSSYPII" APPLIED AND ENVIRONMENTAL MICROBIOLOGY, WASHINGTON, DC, US, Vol. 64, No. 11, November 1998 (1998-11), pages 4283-4290, XP000857901 ISSN: 0099-2240
- D3: US-A1-2002/123118 (ALLEN STEPHEN M ET AL) 5 September 2002 (2002-09-05).

2. The International Searching Authority has found that this international application contains several (groups of) inventions, namely a possible invention:

- 1 Method for producing amino acids by introducing a nucleic acid sequence which encodes a threonine-decomposing protein into an organism
- 2 Method for producing amino acids by introducing a nucleic acid sequence which encodes a threonine-decomposing protein into an organism
- 3-10 Claim 26 (in part) Amino acids whose amino acid sequences are described by the SEQ ID NO. 3-10.

The applicant has not paid the requisite additional search fees within the prescribed time-limit. The international search report is restricted to the invention first mentioned in the claims; consequently, a written report could be established only for claims 1-24, that is, limited to a method

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(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III and V

for producing amino acids by introducing a nucleic acid sequence which encodes a threonine-decomposing protein into an organism (denoted as group 1 in the search report).

3. The present application does not comply with the requirements of PCT Article 33(1), because the subject matter of claims 20-24 is not novel within the meaning of PCT Article 33(2).

It could be argued that the invention relates to a method for producing amino acids, but the subject matter of claims 20-24 is not a method, because these claims are product claims. Document D3 discloses isolated DNA which is identical to SEQ ID NO. 1. Moreover, D1 also discloses constructs which contain said SEQ ID NO., the use thereof, and transgenic organisms comprising at least one of these constructs (D3, claims and pages 48 and 49). Consequently, D3 is prejudicial to the novelty of claims 20-24 (PCT Article 33(2)).

4. The present application does not comply with the requirements of PCT Article 33(1), because the subject matter of claims 1-19 does not involve an inventive step within the meaning of PCT Article 33(3).

Document D1 is considered to be the closest prior art for the subject matter of claim 1. D1 discloses unicellular or multicellular organisms in the method for producing riboflavin. Those organisms have an increased glycine concentration (see, inter alia, D1, page 2, last paragraph and claims). D3 already discloses similar subject matter. The subject matter

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Continuation of: III and V

of claims 1-19 differs therefore from the known D1 or D3 in that a method for producing an amino acid selected from the group consisting of methionine, homoserine and lysine is disclosed. (It should be noted at this point that, because of the wording of the claim, D1 or D3 also disclose this in principle, because the methods applied therein could also be applied for each of the other amino acids, and the claimed method steps are not distinguishable from D1 or D3.)

The problem addressed by the present invention can therefore be considered that of introducing the nucleic acid sequence SEQ ID NO. 1 and its derivatives.

The solution proposed in claim 1 of the present application cannot be considered inventive (PCT Article 33(3)) for the following reasons: D3 discloses SEQ ID NO. 1 as well as its derivatives, which also take part in glycine metabolism. A person skilled in the art could easily and without exercising inventive skill use the sequences disclosed in D3 instead of the sequences disclosed in D1 or D2 in order to produce amino acids. Consequently, the subject matter of claims 1-19 does not involve an inventive step (PCT Article 33(3)).

Moreover, it may be asked whether the technical problem (production of methionine, homoserine, lysine) has been solved at all. A requirement for the establishment of inventive step is that a technical problem must be solved. However, this does not appear to be the case here.

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Continuation of: III and V

5. Transgenic organisms, including organisms of animal origin, are claimed in claim 20. Animal organisms also include humans. It should be noted that there is no uniform opinion in the PCT Contracting States concerning the industrial applicability of subjects of this nature. Under the EPC, such subjects are not patentable.